DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 12, 2014

neoSurgical Ltd.
Ms. Orla Brennan
Quality Assurance/Regulatory Affairs Director
Block 12
Galway Technology Park, Parkmore
Galway, Ireland

Re: K142903
Trade/Device Name: neoClose
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 3, 2014
Received: October 6, 2014

Dear Ms. Brennan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use Statement

510(k) Number:

Device Name: neoClose

Indications for Use: neoClose is intended to facilitate the delivery of absorbable AutoAnchors through soft tissues of the body during endoscopic/laparoscopic surgery.

Prescription Use__X__ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

3. 510(k) Summary

510(k) Summary

I. SUBMITTER

neoSurgical Ltd.
Block 12
Galway Technology Park,
Parkmore,
Galway, Ireland

Phone: +353 (0)91 421 000

Contact Person: Orla Brennan
Date Prepared: October 3rd, 2014

II. DEVICE

Name of Device: neoClose AutoAnchor Pack
Common or Usual Name: Suture Passer
Classification Name: Endoscope and Accessories (21 CRF 876.1500)
Regulatory Class: II
Product Code: GCJ

III. PREDICATE DEVICE

neoClose Hasson and neoClose Universal (K123280; K131688)
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The neoClose AutoAnchor Pack consists of absorbable AutoAnchors and neoClose Drivers. The neoClose AutoAnchor consists of an absorbable suture attached to an absorbable polymeric anchor. There are two distinct product codes: the neoClose 2 AutoAnchor Pack (NCAA2-U) and the neoClose 4 AutoAnchor Pack (NCAA4-U). The neoClose AutoAnchors and Drivers are provided sterile (EtO).

Each neoClose AutoAnchor is pre-loaded on a neoClose Driver. The neoClose Driver is used to deliver an AutoAnchor through the abdominal wall layers into the abdominal cavity for subsequent soft tissue approximation. The neoClose AutoAnchor and Driver are to be used in conjunction with a neoClose Guide.

V. INDICATIONS FOR USE

neoClose is intended to facilitate the delivery of absorbable AutoAnchors through soft tissues of the body during endoscopic/laparoscopic surgery.

The Indications for Use statement for the neoClose AutoAnchor Pack is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate devices are used for the delivery of absorbable AutoAnchors into the abdominal cavity for subsequent soft tissue approximation. At a high level, the subject and predicate devices are based on the following same technological elements:

- Absorbable AutoAnchors are delivered into the abdominal cavity for subsequent approximation of tissue
- A neoClose Driver is used to deliver an AutoAnchor into the abdominal cavity
- The neoClose AutoAnchor and Driver are to be used in conjunction with a neoClose Guide

The following differences exist between the subject and predicate devices:

- The modified neoClose Driver is stiffer than the predicate neoClose Driver
- The modified neoClose Driver has a revised tip design
- An alternative suture has been introduced for the neoClose AutoAnchor
- The packaging has been modified

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

A biological evaluation was conducted for the neoClose AutoAnchor Pack in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA.

The neoClose AutoAnchor is considered a permanent implant, while the neoClose Driver is considered tissue contacting for a duration that is less than 24 hours.

Bench Testing

Bench Testing was conducted for the neoClose AutoAnchor Pack to demonstrate that it is at least as safe and effective as the predicate device.

VIII. CONCLUSIONS

The neoClose AutoAnchor Pack is considered substantially equivalent to the predicate device. It has the same intended use and does not raise new questions regarding safety or effectiveness. It is considered at least as safe and effective as the predicate device when used in accordance with the Instructions for Use.